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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,301	06/29/2001	Daniel J. Cosgrove	P04666US7	3341

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EXAMINER

SAIDHA, TEKCHAND

ART UNIT	PAPER NUMBER
1652	10

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/896301	Applicant(s) Cosgrove
Examiner T. Saidha	Group Art Unit 1652

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE —3— MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- Responsive to communication(s) filed on 6/29/01 (Paper #6 & 9).
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- Claim(s) 10-21 is/are pending in the application.
- Of the above claim(s) 10-13, 17, 19 & 21 is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 14-16, 18 and 20 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ Interview Summary, PTO-413
- Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

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DETAILED ACTION

1. Applicants' Preliminary Amendment filed 6.29.01 (Paper No. 6) is acknowledged. Pending claims 10-21 were subjected to a restriction requirement as per Office Action dated 9.4.02 (Paper No. 8).

2. ***Election***

Applicant's election of group II, claims 14-16, 18 & 20 with traverse in Paper No. 9 is acknowledged. The traversal is on the ground(s) that a thorough search of the prior art polynucleotide is likely to uncover prior art relating to the method of identifying a nucleic sequence & *vice versa*. No separate search would be required. This is not found persuasive because separate search is required and further as shown in the restriction requirement inventions of Group I [class 536/subclass 23.1] and Group II [class 435/subclass 6], have been classified in separate classes and subclasses and therefore meet the criteria set forth in MPEP 808.02. This additional searching as explained above would therefore involve undue burden to the Examiner. The requirement is still deemed proper and is therefore made FINAL.

3. Claims 10-13, 17, 19 & 21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 9.

4. Claims 14-16, 18 & 20 are under consideration in this examination.

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5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

6. ***Drawings***

The Draftsman's objection(s) to the drawings is enclosed here in the notice on form PTO-948.

Correction is required.

7. ***Abstract***

The abstract should be in narrative form and generally limited to a single paragraph within the range of 50 to 250 words. The abstract should not exceed 25 lines of text. Abstracts exceeding 25 lines of text should be checked to see that it does not exceed 250 words in length since the space provided for the abstract on the computer tape by the printer is limited. If the abstract cannot be placed on the computer tape because of its excessive length, the application will be returned to the examiner for preparation of a shorter abstract. The form and legal phraseology often used in patent claims, such as "means" and "said", should be avoided. The abstract should sufficiently describe the disclosure to assist readers in deciding whether there is a need for consulting the full patent text for details. MPEP 608.01(b).

The instant abstract is objected to exceeding 25 lines, even though there are less than 250 words. This step is being taken as a precaution in order to avoid future problems of printing when

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the case goes to issue, which may arise because of space limitation, as explained above. Applicants are advised to suitably limit the abstract.

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

9. The amendment filed 6.29.01 (Paper No. 6) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

No method for the identification of nucleic acid comprising the method steps of claims 14-16, 18 & 20 have been described in the specification or have any basis in the specification, as originally filed. Similarly, no oligonucleotide fragments of contiguous bases of SEQ ID NO : 1 or 'computer algorithm' have any previous described in the specification or have any basis in the specification, as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

10. Claims 14-16, 18 & 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 14-16, 18 & 20 are directed to a method of identifying a nucleic acid comprising ‘an oligonucleotide of any size ’ ..of SEQ ID NO : 1 (claim 14), or fragment of undefined size for a ‘PCR primer’ or a ‘hybridization probe’ (Claims 15-16), or obtaining an oligo-fragment(s) which encodes amino acid sequences of SEQ ID NO : 2-6 or their conservatively modified variants (claim 18) or designing a primer based upon the amino acid sequence of SEQ ID NO : 2. The specification discloses a single cDNA sequence (SEQ ID NO: 1) encoding cucumber cEx-29 expansin protein as the only genus. The method steps are unclear and remains undescribed. No specific oligo-fragments, or hybridization conditions or what amino acid substitution is considered as conservative modification (variants) are described. No representative number of species corresponding to polynucleotides of SEQ ID NO : 1 encoding expansin from other species and/or structure activity relationships are disclosed. There is no prior art disclosure of polynucleotide sequences encoding the catalytic polypeptides (expansin proteins) from diverse plant or animal or microorganism genera that is available in order to compare the only disclosed genus in the instant case. Claims 14-16, 18 & 20 are rejected under this section of 35 U.S.C. 112 because the claims are directed to a method of identifying a nucleic acid comprising ‘an oligonucleotide’ ..of SEQ ID NO : 1 (claim 14) based upon oligo-fragments, or fragment of undefined size for a ‘PCR primer’ or a ‘hybridization probe’ (Claims 15-16), or obtaining an oligo-fragment(s) which encodes amino acid sequences of SEQ ID NO : 2-6 or their conservatively modified variants (claim 18) or designing a primer based upon the amino acid sequence of SEQ ID NO : 2. and no representative number of species of polynucleotides, are disclosed. Further, not a single ‘oligonucleotide fragment’ or ‘primer’ of any size pertaining to SEQ

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ID NO : 1 is described. A ‘representative number of species’ requires that the species which are expressly described be representative of the entire genus. Thus, when there is substantial variation within the genus, it may require a description of the various species which reflect the variation within the genus. In the instant case, the specification fails to describe even a single ‘oligonucleotide fragment’ or ‘primer’ of SEQ ID NO : 1 or any representative species of SEQ ID NO : 1 by structure and/or physical and chemical characteristics, representative of the entire genus which includes any catalytic polypeptide [expansin] from any source - plant, animal or microorganism, etc. What constitutes a ‘representative number’ is an inverse function of the predictability of the art. The number must be sufficient to identify the other members of genus. In an relatively unpredictable art, such as the instant one, wherein the cDNA is novel but lack comparison to other related expansin cDNAs, adequate written description requirement of a genus cannot be achieved by disclosing only one species [in the sequence of SEQ ID NO : 1] within the genus. In such a case, where the members of the genus being claimed are expected to vary widely in their identifying characteristics, such as structure or activity, written description for each member within the genus will be necessary. Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

11. Claims is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for :

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‘A method for identifying a nucleic acid sequence which encodes a protein with expansin activity, comprising the steps of isolating the nucleic acid sequence from a cDNA library by hybridization (under defined stringency conditions) using a DNA probe comprising all of the sequence of SEQ ID NO : 1’,

does not reasonably provide enablement for a method of identifying a nucleic acid comprising ‘an oligonucleotide of any size ’ ..of SEQ ID NO : 1 (claim 14), or fragment of undefined size for a ‘PCR primer’ or a ‘hybridization probe’ (Claims 15-16), or obtaining an oligo-fragment(s) which encodes amino acid sequences of SEQ ID NO : 2-6 or their conservatively modified variants (claim 18) or designing a primer based upon the amino acid sequence of SEQ ID NO : 2. Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988))[*Ex parte* Forman [230 USPQ 546 (Bd. Pat. App. & Int. 1986)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim. The factors most relevant to this rejection are the scope of the claims, unpredictability in the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

The claim is drawn to encompass a method of identifying a nucleic acid using ‘an oligonucleotide of any size ’ ..of SEQ ID NO : 1 (claim 14), or fragment of undefined size for a ‘PCR primer’ or a ‘hybridization probe’ (Claims 15-16), or obtaining an oligo-fragment(s) which encodes

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amino acid sequences of SEQ ID NO : 2-6 or their conservatively modified variants (claim 18) or designing a primer based upon the amino acid sequence of SEQ ID NO : 2. The specification, however, only discloses a single polynucleotide encoding a cucumber cEx-29. In addition the specification teaches the amino acid sequences (SEQ ID NO : 2 to SEQ ID NO : 5) of expansins from rice and *Arabidopsis*. Expansins are a new class of proteins that have been identified to be involved in cell wall expansion. Recent studies [Shcherban et. al, PNAS (1995, Sep 26), 92 (20) : 9245-9, not prior art] have identified 4 distinct expansins cDNA in rice and at least 6 in *Arabidopsis* and show that the expansins from among these plant species, are highly conserved in size and sequence similarity (60-87 % amino acid sequence identity). Searching for sequence homology and comparison of amino acid sequence homology of expansin from Strawberry (AC : W81347), for example, and Applicants' amino acid sequence from *Arabidopsis* expansin (SEQ ID NO. 5) show a sequence homology of about 48.9%; and a nucleotide sequence homology of 25% between Applicants' SEQ ID NO : 1 (cucumber expansin cDNA, AC : T13320) and the nucleotide sequence of strawberry expansin (AC : V68447). Such a low nucleotide sequence homology is not always sufficient to use the Applicants' SEQ ID NO : 1 as a probe in order to clone the expansin polynucleotide from strawberry, even under high stringency conditions. So, if one skilled in the art were to use a fragment of SEQ ID NO : 1 as probe in order to clone similar genes, based upon the homology factor discussed above, the chances of successful hybridization are extremely low, in view of the unpredictable nature of the art, as well as inadequate guidance provided in the specification.

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Thus the claims are directed to specifically encompass enormous numbers of embodiments expected to be inoperative. Since it is not routine in the art to engage in experimentation to develop method of first designing suitable polynucleotide probes which would aid in identifying other nucleic acid sequences encoding protein(s) having expansin activity, where the expectation "of success is unpredictable", the skilled artisan would require additional guidance in order to make and use the claimed method in a manner reasonably commensurate with the scope of the claim. Without such guidance, the experimentation left to those skilled in the art is undue.

12. Claim 14-16 & 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14, line 3, recites : 'contiguous basis from SEQ ID NO : 1'. Spelling of 'basis' is incorrect.

Correcting basis to read bases is suggested to overcome this rejection.

Claim 14, line 5, recites 'computer algorithm based assay'. It is unclear what is meant by the phrase and the specification does not define the meaning of the phrase. Using an art accepted phrase or suitable modification will overcome this rejection.

Claim 20, lines 3-4 recite 'SEQUENCE ID NO : 2', which is not the accepted format. Rewriting the phrase to read as - 'SEQ ID NO : 2', is suggested to overcome this rejection.

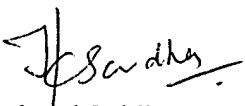
Claims 15-16 are included in the rejection for failing to correct the defect present in the base claim(s).

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (703) 305-6595. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group in the Technology Center is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Tekchand Saidha
Primary Examiner, Art Unit 1652
November 21, 2002